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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,212	06/23/2000	Ursula Buchholz	15280-398100US	9937

7590 07/29/2003

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EXAMINER
BROWN, STACY S

ART UNIT	PAPER NUMBER
1648	24

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/602,212	BUCHHOLZ ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-101* is/are pending in the application.

4a) Of the above claim(s) *30-45,48-56,83,84,88,89,93,94,96,97,100 and 101* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29,46,47,57-82,85-87,90-92,95,98 and 99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment filed June 10, 2003 is acknowledged and entered. Claims 1-29, 46, 47, 57-82, 85-87, 90-92, 95 and 98-99 are pending and examined. Claims 30-45, 48-56, 83, 84, 88, 89, 93, 94, 96, 97, 100 and 101 are withdrawn from consideration. The objection to the abstract and to claims 14, 24, 61, 72, 98 and 99 are withdrawn in view of Applicant's amendment. The rejection of claims 46, 47 and 97 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendment.

Priority

2. The rejection of claims 1-2, 6-8, 16, 46, 63-66, 73, 82 and 90 are rejected under 35 U.S.C. 102(a) as being anticipated by Buchholz *et al* (Virology, 1999) is withdrawn in view of the new priority claim. The rejection of claims 1-29, 46-47, 57-82, 85-87, 90-92, 95, 98 and 99 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy *et al* (WO 98/02530) is withdrawn in view of the new priority claim. The rejection of claims 1-29, 46-47, 57-82, 85-87, 90-92, 98 and 99 are rejected under 35 U.S.C. 102(e) as being anticipated by Collins (6,364,957) is withdrawn in view of the new priority claim.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(New Rejection) Claims 1-29, 46, 47, 57-82, 85-87, 90-92, 95 and 98-99 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims read on embodiments of the claimed chimeric RSV wherein the virus comprises a RNA polymerase elongation protein. Thus, the claims as written encompass a generic class of chimeric RSV viruses, each of which may contain any RNA polymerase elongation factor. The specification does not provide adequate written description support for the full scope of these generic claims.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Also relevant to the discussion are the following excerpts from the case of In re Borkowski and Van Venrooy, 164 USPQ 642, (CCPA 1970). In describing the appropriate grounds for a claim rejection when the claim exceeds the scope of the disclosure, the court stated the following:

> *...a specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation.* (Excerpt from164 U.S.P.Q. at 645)

and;

> *... if the "enabling" disclosure of a specification is not commensurate in scope with the subject matter encompassed by a claim, that fact does not render the claim imprecise or indefinite or otherwise not in compliance with the second paragraph of §112; rather, the claim is based on an insufficient disclosure 4 (§112, first paragraph) and should be rejected on that ground. See In re Fuetterer, 50 CCPA 1453, 319 F.2d 259, 138 USPQ 217 (1963); In re Kamal, 55 CCPA 1409, 398 F.2d 867, 158 USPQ 320 (1968); and In re Wakefield, 164 USPQ (PA 8192), decided concurrently herewith. Thus, just as a claim which is of such breadth that it reads on subject matter disclosed in the prior art is rejected under §102 rather than under the second paragraph of §112, a claim which is of such breadth that it reads on subject matter as to which the specification is not "enabling" should be rejected under the first paragraph of §112.* (Excerpt from 164 U.S.P.Q. at 646).

Thus, when a claim covers a genus of inventions the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed. However, a disclosure will also support the claims in the absence of examples if the description would enable one in the art to practice the invention without such guidance.

In the present case, the applicant has disclosed only a single example of a RNA polymerase elongation factor- the M2 ORF 1 protein of RSV. See e.g., page 20, lines 4-6. sbc Although the specification states that M2 ORF1 is only a preferred embodiment, neither the description nor the examples in the application provide any indication of what equivalents may be. Without examples, or some identification of the M2 ORF1 structure that is necessary to its operation, one in the art wishing to practice the invention has no indication as to what other proteins may be used in the claimed virus. In view of the lack of description for any RNA polymerase elongation factor other than the M2 ORF1, the claims are rejected for exceeding the scope of descriptive support provided by the specification.

4. Claims 1-29, 46, 47, 57-82, 85-87, 90-92, 95 and 98-99 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated infectious recombinant RSV wherein the virus comprises the M2 (ORF1) RNA polymerase elongation factor, does not reasonably provide enablement for viruses containing any RNA polymerase elongation factor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

A claim is commensurate in scope with the enablement when the applicant has provided sufficient disclosure to enable one skilled in the art to practice the claimed invention without undue experimentation. In re Wands, 8 USPQ2d 1400, 1404 (CAFC 1988). There must be a "reasonable correlation" between the scope of enablement and the scope of the claims. In re Fisher, 166 U.S.P.Q. 18, 24 (CCPA 1970). Such correlation requires "sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility." See, In re Vaeck, 20 U.S.P.Q.2d 1438, 1444 (CAFC 1991) No such guidance is provided in the present case.

The art relevant to the claimed invention (Collins *et al. PNAS USA* 92:11563-11567) indicates that the M2 ORF1 protein is one of the minimal proteins necessary for an infectious RSV (see abstract). Although the specification states that M2 ORF1 is only a preferred embodiment, it does not identify any characteristic or examples which one of ordinary skill in the

art could use as guides to identify equivalents. Given the teachings of the specification and the disclosure of Collins, M2 ORF1 protein is necessary for an operative recombinant RSV. As the application has provided no examples or other indication as to what proteins fall within this subclass, other than the M2 ORF1 protein itself, the application has not provided an enabling disclosure corresponding to the full scope of the rejected claims.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-29, 46, 47, 57-82, 85-87, 90-92, 95 and 98-99 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10, 11 and 22 of U.S. Patent No. 6,264,957. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are a species of the genus instantly claimed. The instant claims are drawn to a chimeric RSV (human/bovine). The claims of the patent are drawn to a chimeric RSV having aM2(ORF1) RNA polymerase elongation factor. The specific elongation factor is a species of the elongation factor instantly claimed.

Conclusion

6. No claim is allowed. The claims are free of the prior art.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stacy B. Chen
July 25, 2003

JAMES HOUSEL 7/28/03
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